UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,092	01/11/2002	Jolyon Jesty	0974/1F828-US1	6018

7278 7590 05/19/2005

DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,092	JESTY ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 28, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

pp

DETAILED ACTION

Examiner acknowledges Applicants' Reply filed February 28, 2005, which amended claims 1-8 and 11-19, and cancelled claims 9-10. Currently, claims 1-8 and 11-20 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

The indicated allowability of claims 6-7 and 16 is withdrawn in view of Applicants' amendment.

Specification

The disclosure is objected to because of the following informalities:

> On page 6, the paragraph beginning "The term 'platelet activation state'...", the recitation of "thrombinase" in the last sentence is indefinite because it is not clear what enzyme is referenced.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-8 and 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 13, the recitation of "the property" lacks antecedent basis and is indefinite because it is not clear what physical structures and/or procedural steps are required for "said product" or "said substrate" to have "the property."

In claim 1, the claim preamble does not appear to correspond to the method outcome. For example, the preamble recites "a method for assaying activation state of platelets" while step b recites the step of "assaying a [thrombin] product." It is not clear how "assaying a [thrombin] product" amounts to an assay for "activation state of platelets."

In claim 4, the recitation of "exogenous" is indefinite because the point of reference(s) defining the boundary between "exogenous" and "not exogenous" is/are not clear.

In claims 13-14, the recitation of "an assay of said product" is indefinite because it is not clear what compounds and/or instruments are encompassed by "an assay." In claim 14, it is not clear what compounds and/or instruments are encompassed by each of the recited Markush members.

Claim Rejections - 35 USC § 103

Claims 1-4, 7-8, 11, 13-14, 16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henriksen et al., 66 J. CLIN. INVEST. 934 (1980), in view of Hemker & Wagenvoord (US 5,266,462).

Henriksen et al. describe a method for assaying prothrombin activation comprising the steps of: providing a mixture comprising a prothrombin-converting enzyme (see p. 935, col. 1, line 9, "taipan snake venom", line 19, "factor Xa"), and a substrate of said prothrombin-converting enzyme (see p. 935, col. 1, line 8, "prothrombins"), assaying a product (see p. 935, col. 1, line 10, "thrombin and thrombin Quick

concentrations were determined"), said product having the property that said product does not activate platelets (see Abstract, "1/20-1/50 as effective in activating Factors V and VIII and aggregating platelets").

Henriksen et al. do not teach a mixture comprising platelets.

However, Hemker & Wagenvoord teach a method using platelets (see Title) for assaying prothrombin activation (see col. 3, lines 47-49). Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method for assaying prothrombin activation, as described by Henriksen et al., with a mixture comprising platelets because Hemker & Wagenvoord confirmed that assaying prothrombin activation in the presence of platelets "is a good tool to measure the susceptibility of platelets to thrombin induced activation" (see col. 9, lines 4-6), and is useful in the development of drugs that inhibit platelet aggregation (see col. 15, lines 19-21).

With respect to claim 2, Henriksen et al. describe a method comprising a modified thrombin product (see p. 935, col. 1, line 10, "thrombin Quick concentrations were determined").

With respect to claim 3, Henriksen et al. describe a method comprising assaying a catalytic activity of said modified thrombin (see Table I, Fibrinogen).

With respect to claim 8 and 14, Henriksen et al. describe a method comprising a fluorescence proximity assay (see Fig. 4).

With respect to claim 11, Henriksen et al. describe a method comprising detecting cleavage of a peptide (see Table I, Fibrinogen).

With respect to claim 20, Henriksen et al. describe a method comprising a syringe (see p. 935, col. 1, second full paragraph, "venipuncture") and water (see p. 935, col. 1, fifth full paragraph).

Claims 5-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henriksen et al., 66 J. CLIN. INVEST. 934 (1985), and Hemker & Wagenvoord (US 5,266,462) as applied to claims 1, 2 and 13, and further in view of Harris & Kozlowski (US 6,541,543).

Henriksen et al. and Hemker & Wagenvoord describe a method for assaying prothrombin activation as substantially described supra. The aforementioned references do not teach a prothrombin chemically derivatized with an acetyl group donated by sulfo-N-succinimidyl acetate.

However, Harris & Kozlowski teach the use of sulfo-N-succinimidyl acetate (see col. 15, lines 60-61) for derivatizing proteins. Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of Henriksen et al. and Hemker & Wagenvoord with prothrombin chemically derivatized with sulfo-N-succinimidyl acetate because Harris & Kozlowski discovered that sulfo-N-succinimidyl acetate increases protein solubility and decreases immunogenicity (see col. 4, lines 61-65).

Claims 12 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henriksen et al., 66 J. CLIN. INVEST. 934 (1985), and Hemker & Wagenvoord (US 5,266,462) as applied to claims 1-3, 11 and 13, and further in view of Lottenberg et al., 80 METHODS ENZYMOL. 341 (1981).

Henriksen et al. and Hemker & Wagenvoord describe a method for assaying prothrombin activation as substantially described supra. The aforementioned references do not teach a Tos-Gly-Pro-Arg-pNA chromogenic peptide.

However, Lottenberg et al. teach the use of Tos-Gly-Pro-Arg-pNA chromogenic peptide (see Table II) for assaying thrombin activity. Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of Henriksen et al. and Hemker & Wagenvoord with Tos-Gly-Pro-Arg-pNA chromogenic peptide because Lottenberg et al. teach peptides provide a sensitive assays having the convenience of spectrophotometric or fluorometric measurements (see p. 341, Introduction).

Response to Arguments

In the Office Action dated July 23, 2004, claims 1-5, 8-15 and 17-20 were rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) in view of Szczeklik et al., 80 BLOOD 2006 (1992). These rejections are withdrawn in light of Applicants' amendment to the claims. Discussion of Szczeklik et al. is rendered moot.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
05/16/05